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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,494	09/06/2005	Louis Schofield	18611	4482

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EXAMINER	
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ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/522,494	SCHOFIELD, LOUIS	
	Examiner	Art Unit	
	Rodney P. Swartz, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15July2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,8,15-22,28,33,38-47,49,50,52-56,60-63 and 66-74* is/are pending in the application.

4a) Of the above claim(s) *43-47,69-71* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,8,15-22,28,33,38-42,49,50,52-56,60-62,66-68 and 72-74* is/are rejected.

7)☒ Claim(s) *15,39,50,55,56 and 63* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *6January2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/07*.

4)☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.

5)☐ Notice of Informal Patent Application

6)☐ Other: _____.

DETAILED ACTION

1. Applicant's Response to Restriction Requirement, received 15 July 2008, is acknowledged. Applicant elects, with traverse, Invention I, claims 1-42 and 49-65, drawn to inositolglycan domain portion of GPI.

Applicant's traversal is on the grounds that the feature central to both Invention I and Invention II is the use of a GPI molecule which lacks a lipidic domain such that antibodies to the lipidic domain are not generated. This is not found persuasive because the antibodies of Invention II are not restricted to only those antibodies which do not bind a lipidic domain, but which are only "substantially" incapable of interacting with the lipidic domain of a GPI. Thus, the antibodies encompassed by the Invention II may include those produced by a natural infection by *P. falciparum* and whose binding characteristics are not dependent upon the GPI of Invention I.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1, 8, 15-22, 28, 33, 38-45, 49, 50, 52, 53, and 61-63 have been amended. Claims 2-7, 9-14, 23-27, 29-32, 34-37, 48, 51, 57-59, 64, and 65 have been canceled. New claims 66-74 have been added.

Claims 1, 8, 15-22, 28, 33, 38-47, 49, 50, 52-56, 60-63 and 66-74 are pending. Claims 43-47 and 69-71 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

Claim 63 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from multiple dependent claims. See MPEP § 608.01(n). Accordingly, the claim has not been further treated on the merits.

3. Claims 1, 8, 15-22, 28, 33, 38-42, 49, 50, 52-56, 60-62, 66-68 and 72-74 are under consideration.

Specification

4. The disclosure is objected to because of the following informalities:

Abstract, lines 3 and 8, "utilising" should be "utilizing".

Page 9, line 4, "characterised" should be "characterized".

Page 10, line 20, "characterised" should be "characterized".

Page 12, line 9, "analysing" should be "analyzing"; line 11, "utilising" should be "utilizing".

Page 13, line 14, what is meant by "(1,5)"; line 25, what is meant by "synergizy".

Page 15, line 27, "centre" should be "center".

Page 18, lines 4 and 10, "immunised" should be "immunized"; line 9, "immunisation" should be "immunization"; lines 16 and 18, "minimising" should be "minimizing"; line 18, "minimised" should be "minimized".

Page 21, line 13, "synthesised" should be "synthesized".

Page 24, line 29, "utilised" should be "utilized".

Page 26, line 23, "immunisation" should be "immunization".

Page 27, line 4, "neutralising" should be "neutralizing".

Page 33, line 19, "synthesise" should be "synthesize".

Page 44, line 23, "sterilisation" should be "sterilization".

Page 47, line 8, "neutralising" should be "neutralizing; line 12, "utilised" should be "utilized".

Page 50, line 10, "utilising" should be "utilizing".

Page 69, there is nothing on this page.

Page 73, line 5 "*P falciparum*" should be "*P. falciparum*"; line 22, "hydrolysed" should be "hydrolyzed".

Appropriate correction is required.

Drawings

5. Figure 1 is objected to because in the legend, "titre" should be "titer".

6. Figure 3 is objected to because in the legend, "titre" should be "titer".

7. Figure 11 is objected to under 37 CFR 1.83(a) because it fails to show "other pathologies" as described in the specification (page 14, lines 16-18). Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing.

Figure 11 is also objected to because neither the x-axis nor y-axis is labeled.

Figure 12 is objected to because both the x-axis and y-axis are labeled "% Survival".

8. Figure 14 is objected to under 37 CFR 1.83(a) because it fails to show "open square" as described in the specification (page 15, line 18). Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing.

9. Figure 19 is objected to because the one axis is not labeled.

10. Figure 20 is objected to because the one axis is not labeled.

11. Figure 21 is objected to because the one axis is not labeled.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet,

even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

12. Claim 15 is objected to because of the following informality: line 2, "characterised" should be "characterized". Appropriate correction is required.

13. Claim 39 is objected to because of the following informality: line 2, "*Plasinodium*" should be "*Plasmodium*". Appropriate correction is required.

14. Claim 50 is objected to because of the following informality: line 6, "phosphoglyucerol" should be "phosphoglycerol". Appropriate correction is required.

15. Claim 55 is objected to because of the following informality: line 2, "*falcipanim*" should be "*falciparum*". Appropriate correction is required.

16. Claim 56 is objected to because of the following informality: line 2, "*Plasinodium*" should be "*Plasmodium*". Appropriate correction is required.

Claim Rejections - 35 USC § 112

17. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

18. Claims 15-22 and 66-68 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15 recites the term "condition characterised by a parasite infection". The specification does not define the metes and bounds of the term "characterized". Thus, it is unclear what may be included or excluded as a condition "characterised by" a parasit infection.

Claims 16-22 and 66-68 are dependent claims, but do not clarify the indefiniteness.

19. Claims 20, 21, 41, 42, 49, 52-56, 60-62 and 72-74 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 20, 21, 41, 42, 49, 52, 53, 61 and 62 recite the phrase "derivative or equivalent thereof". While the specification does recite examples of said derivatives/equivalents, the specification does not actually define the metes and bounds of the terms. Thus, it is unclear what may be included or excluded as a "derivative" or "equivalent" thereof.

Claims 54-56 and 72-74 are dependent claims, but do not clarify the indefiniteness.

20. Claim 22 is rejected under 35 U.S.C. 112, second paragraph, because the claim recites the limitation of the method according to claim 1 "wherein said disease condition is malaria". There is insufficient antecedent basis for this limitation in the claim because claim 1 does not recite "disease condition".

21. Claims 28, 33, 38-42 and 66-68 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 28, 33, and 38 recite the term "substantially". The specification does not define the metes and bounds of the term. Thus, it is unclear what may be included or excluded as a "substantial" characteristic.

Claims 39-42 and 66-68 are dependent claims, but do not clarify the indefiniteness.

22. Claims 1, 8, 15-22 and 66-68 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 8, and 15 recite "an effective amount" of a composition which comprises the inositolglycan domain portion of GPI, which inositolglycan domain portion comprises "insufficient lipidic domain to induce or elicit an immune response directed to said lipidic domain".

It is unclear what is the relationship between "an effective amount" of said composition and the level of lipidic domain. That is, in said composition, the amount lipidic domain is to be kept so low that under no amount of GPI is there to be an immune response to said lipidic domain, or, that under the minimum amount of GPI that elicits an immune response there is no response to said lipidic domain.

Claims 16-22 and 66-68 are dependent claims, but do not clarify the indefiniteness.

23. Claims 50, 52-62 and 72-74 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 50 is drawn to a method for detecting, monitoring or otherwise assessing an immune response directed to a microorganism in a subject, said method comprising contacting a biological sample from said subject with a domain molecule, and qualitatively and/or quantitatively screening for "said" domain-immunointeractive molecule complex formation.

It is unclear what is meant by "otherwise assessing" an immune response. Also, it is unclear about the antecedent basis for "said" complex formation.

Claims 52-62 and 72-74 are dependent claims, but do not clarify the indefiniteness.

Conclusion

24. No claims are allowed.

25. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's Supervisor, Robert B. Mondesi (571)272-0956.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

October 10, 2008